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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/482,402 06/07/95 RAPOPORT

B 102105-15101

EXAMINER

HM12/0214

DONALD E. STOUT
STOUT, UXA, BUYAN & MULLINS, LLP
4 VENTURE, SUITE 310
IRVINE CA 92618

UNRAR.S

ART UNIT

PAPER NUMBER

1642

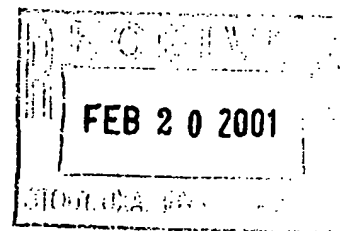
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks



Office Action Summary

Application No.

08/482,402

Applicant(s)

Rapoport

Examiner

Ungar

Group Art Unit

1642

☒ Responsive to communication(s) filed on Nov 14, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 37-59 is/are pending in the application.

Of the above, claim(s) 37, 47, and 57 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 38-46, 48-56, 58, and 59 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 34

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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1. The Amendment filed November 14, 2000 (Paper No. 35) in response to the Office Action of August 22, 2000 (Paper No. 33) is acknowledged and has been entered. Previously pending claims 38 and 48 have been amended and new claims 58-59 have been added. Claims 38-46, 48-56 and 58-59 are currently being examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The following objections are maintained:

Objection to the Brief Description of the Drawings imposed in Paper No. 12, Section 5, page 3 is maintained because the specification has not been amended to describe Figure 7, panels A-F.

Objection to the specification imposed in Paper No. 25, Section 5, page 2 is maintained because the specification has not been amended to reflect the status of the parent applications. The objection can be obviated by amending the specification to recite, for example, "divisional of United States Application Serial No. 08/196,082 filed March 3, 1994, now abandoned".

Objection to the Declaration and requirement for certified copies of the PCT's imposed in Paper No. 25, Section 3, page 7 is being maintained, pending submission of the required papers.

4. The following rejections are maintained:

Claim Rejections - 35 USC § 112

5. Claims 38-46 and 48-56 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 33, Section 5, page 3.

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Applicant argues that page 5 of the specification supports the limitation of “thyroiditis”. The argument has been considered but has not been found persuasive because a review of page 5 reveals that “the recombinant hTPO of this invention is recognized in a specific manner by sera from patients with Hashimoto’s thyroiditis”. However, there is no support for or even a contemplation of binding by the broadly worded “antibody associated with thyroiditis”. The subject matter claimed in claims 38-46 and 48-56 broadens the scope of the invention as originally disclosed in the specification. Applicant's arguments have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 102

6. Claim 38 remains rejected under 35 USC 102, and newly added claim 58 is rejected under 35 USC 102, for the reasons previously set forth in Paper No. 33, Section 8, pages 4-5.

Applicant argues that Libert et al does not anticipate the present invention because Libert et al discloses a full length human peroxidase whereas the present claims are directed to truncated human thyroid peroxidase. The argument has been considered but has not been found persuasive because Applicant is arguing limitations not recited in the claim as presently constituted. The claim clearly reads on “a human thyroid peroxidase” and is not limited to a truncated human thyroid peroxidase. Applicant's arguments have not been found persuasive and the rejection is maintained.

(Truncated form)

Claim Rejections - 35 USC § 103

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7. Claims 38-46 and 48-56 remain rejected under 35 USC 103, and newly added claims 58-59 are rejected under 35 USC 103, for the reasons previously set forth in Paper No. 33, Section 8, pages 4-5.

Applicant argues that (a) Examiner alleges that “Rose et al teaches that antibodies that bind to the full length protein may also bind to the truncated secretable variant”, (b) Examiner has not shown that one of ordinary skill would have expected there to be a likelihood of success in arriving at the claimed invention in light of the cited references since the Rose et al reference protein is different from the protein of the present invention in that it is intracellular rather than extracellular. Applicant further points out that both the protein of Rose et al and the instantly claimed protein are membrane bound with the same hydrophilic COOH terminus but that the two proteins undergo different biogenesis, (c) the truncated protein of Rose et al is secreted slowly which is different than the truncated hTPO of the present invention which is secreted rather “quickly”, (d) Applicant argues that thyrotropin receptor cannot be produced by removing its transmembrane portion and cites Chazenbalk et al, (e) the courts have recognized that chemical and biological art such as the present invention are unpredictable, (f) because Rose does not predict that there is any likelihood of success that a truncated hTPO can be secreted, it cannot predict that truncated hTPO may be recognized by an autoantibody since an antibody recognizes a protein by the protein’s very specific three dimensional structure and since protein chemistry is unpredictable, the three dimensional conformation of the truncated protein cannot be determined (g) EP013417 is irrelevant because it only teaches that a truncated polypeptide has the same

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antigenic determinants as the full length membrane bound polypeptide and there is a significant difference between using a truncated polypeptide to raise an antibody which recognizes a full length peptide and generating a truncated polypeptide which is able to bind a pre-existing antibody where the pre-existing antibody is raised to a full length polypeptide.

The arguments have been considered but has not been found persuasive because “(a’) contrary to Applicant’s reading of Examiner’s statement drawn to Rose, Applicant is directed to page 7 of Paper No. 33 where Examiner specifically states that antibodies that bind to the full length protein **also** (emphasis added) bind to the truncated secretable form of the protein. There was **no** (emphasis added) speculation involved with this statement, (b’) given the teaching of the combined references, one of ordinary skill would have a reasonable expectation of success in producing the truncated protein of the invention because Rose et al specifically teach the production of a truncated secretable polypeptide with the same membrane anchor as the protein claimed and further specifically teach that antibodies that bind to the full length protein also bind to the truncated secretable variant which clearly demonstrates that the truncated and secretable form of the transmembrane protein retains its structure as well as its ability to bind antibodies bound by the full length protein. The differences in biogenesis and membrane location would not be expected to alter the structural result produced when the truncation of both proteins involves the deletion of the same membrane anchor, (c’) the truncated version is secreted and further, Applicant is arguing limitations not recited in the claims as presently constituted, (d’) the argument is not persuasive for the reasons previously

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set forth in Paper No. 23, Section 2(b), pages 2-4, (e') given the combined teachings of the prior art one of ordinary skill would have motivation for and a reasonable expectation of success in producing a truncated hTPO for the reasons previously set forth, (f') Rose et al specifically teach that the truncated secreted protein bound the same antibodies that bound the full length protein, thus demonstrating that truncated protein retains the structure of the full length protein, (g') the production source of the binding antibody is not relevant since it is clear that EP0139417 clearly teaches that both the truncated and full length polypeptide have the same antigenic determinants which clearly bind the same antibody, (f) and (g) Applicant has argued and discussed the references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

New Grounds of Objection

8. The Figures and the Brief Description of the Figures are objected to because, in view of the amendments to the specification, neither the Figures nor the Brief Description of the Figures are in consecutive numerical order. Appropriate correction is required.

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9. Figures 6, 7, 18 and 19 are objected to because neither the Figures themselves nor the Brief Description of Figures disclose unique identifiers in the form of SEQ ID Nos for the disclosed sequences. It is noted that all amino acid sequences of four or more amino acids and all nucleotide sequences of ten or more nucleotides must be identified by unique SEQ ID Nos which correspond to numbers listed in both the computer readable and paper Sequence Listings. Appropriate correction is required.

New Grounds of Rejection

10. Claims 38-46, 48-56 and 58-59 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 38-46, 48-56 and 58-59 are indefinite because claims 38 and 48 recite the phrase "is recognized by an antibody associated with thyroiditis". The claims are confusing because it is not clear how the antibody is associated with thyroiditis. The rejection can be obviated by amending the claims to read, for example "is recognized in a specific manner by sera from patients with Hashimoto's thyroiditis" as recited on page 5 of the specification.

11. All other objections and rejections recited in Paper No. 33 are withdrawn.

12. No claims allowed.

13. Applicant's amendment necessitated the new grounds of rejection.

Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

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A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1640.

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A handwritten signature in black ink, appearing to read "Susan Ungar", with a stylized flourish extending from the end.

Susan Ungar

Primary Patent Examiner

February 2, 2001